determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with HCFA to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for ''premarket approval'' and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at §411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at §411.15(o) of this chapter, the FDA notifies the sponsor and HCFA and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because HCFA determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises